DEC 21 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
CEA Assay for Bayer ADVIA® Integrated Modular System (IMS)™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013568

1. Intended Use

This *in vitro* immunoassay is intended to quantitatively measure CEA in human serum using ADVIA IMS CEA Assay on a *Bayer ADVIA®* IMS™. Carcinoembryonic Antigen (CEA) is a protein polysaccharide normally present at very low concentrations in the blood of healthy adults. Colorectal cancer and a variety of neoplastic and other disease processes cause significant elevation of CEA, thus issued as a tumor marker. CEA assay is designed to aid in the management and prognosis of cancer patients in whom changing concentrations of CEA are observed.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #	K #
Immuno 1 CEA Assay	T01-3184-51	T03-3188-01	P940030; down classified to 510(k)

3. Device / Method

Product Name	Reagent Part # / BAN Number	Calibrator Part # / BAN Number
ADVIA IMS CEA Assay	B42-3897-42 / 00610885 (100 tests) 01075029 (250 tests)	B43-3929-01 / 02918372

Imprecision

ADVIA IMS	
Level (ng/mL)	Total CV(%)
2.05	3.0
10.76	2.2
16.85	1.8

Immuno 1	
Level (ng/mL)	Total CV(%)
2	5.3
12	4.3
24	4.3

Correlation (Y= ADVIA IMS, X=comparison system)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	89	0.973 * X+ 0.093	1.019	0.998	0.51-76.25

Interfering Substances

Interfering Substance	Interfering Substance Concentration mg/dL	CEA Concentration (ng/mL)	Effect (% change)
Hemoglobin	1000	2.01	0.4
Lipids (Triglycerides)	1000	1.6	1.8
Bilirubin	25	2.11	1.2
IgG	6.0	1.85	1.2
Albumin	6.5	1.71	2.5

Analytical Range
0.2 – 100 ng/mL

Minimum Detectable Concentration

ADVIA IMS (ng/mL)	Immuno 1 (ng/mL)
0.2	0.2

4. Conclusion

Performance of the ADVIA IMS CEA Assay on a *Bayer ADVIA®* IMS™ is equivalent to the performance of the CEA Assay on the predicate device (Immuno 1) and is within proposed specifications. No safety and effectiveness issues have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k013568
Trade/Device Name: Carcenoembroyonic Antigen Assay for the Advia IMS
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: DHX
Dated: October 24, 2001
Received: October 26, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K013568

Device Name: Carcenoembroyonic Antigen Assay for the Advia IMS

Indications for Use:

The *Bayer ADVIA® IMS™* CEA assay is an *in vitro* diagnostic device intended to quantitatively measure carcinoembryonic antigen (CEA) in human serum. CEA test results aid in the management of cancer patients by monitoring CEA concentrations. ***CEA testing is not recommended as a screening procedure to detect cancer in the general population.***

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan S. Alaire

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013568

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)